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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/500,213	02/08/2000	Mark G. Schrom	16724-108	2262

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 11/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/500,213

Applicant(s)

SCHROM ET AL.

Examiner

George R Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 16-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15, drawn to a lead, classified in class 607, subclass 116.
- II. Claims 16-35, drawn to a method of fabricating a lead, classified in class 29, subclass 746.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process not involving extruding a body member, but by injection molding the body member, and not involving creating a plurality of openings before forming the electrode, but by creating the openings through the electrode after the electrode is formed.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Kevin Cyr on 10/29/02 a provisional election was made with traverse to prosecute the invention of group I, claims 1-15. Affirmation of this election must be made by applicant in replying to this Office action. Claims 16-35 are

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withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, "deposited on said..." is vague since it sounds more like a method step than a structural recitation. In step (e), "conductive links...through said tunnel" is vague since only one conductive link can go through the tunnel. It is suggested to use "a conductive link extending through each said at least one tunnel".

Claim 2 needs a period at the end of it.

In claims 2, 3 and 14, the claim is mixing the use of "at least one" with a plurality of elements. As an example, claim 1 has recited "at least one conductor" while claim 2 has recited "the conductors" and it is unclear if there is at least one conductor or a plurality of conductors.

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In each instance the examiner has interpreted the claims as having "at least one" of those elements.

In claims 6, 11 and 15, the claims are improper Markush groupings. It is suggested to use "selected from the group consisting of..."

In claims 8 and 9, "said plurality of conductors" lack antecedent basis.

In claim 13, "said plurality of electrodes" lacks antecedent basis.

In claim 15, "said ring electrodes" lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, and 10-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Willis (5433742). For claim 14, the electrodes are overlapped in relation to the longitudinal direction. For claim 10, the recitation of "electroplated" is more like a method step than a structural

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limitation (the claimed limitation is directed to how the element is produced and is structurally equivalent to Willis's conductive links).

Claims 1-3 and 10-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Champeau (6208881). For claim 10, the recitation of "electroplated" is more like a method step than a structural limitation (the claimed limitation is directed to how the element is produced and is structurally equivalent to Champeau's conductive links).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gotthardt et al (5016646 in view of Willis (5433742). For claim 10, the recitation of "electroplated" is more like a method step than a structural limitation (the claimed limitation is

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directed to how the element is produced and is structurally equivalent to Gotthardt in view of Willis's conductive links).

Gotthardt discloses the claimed invention except for the electrodes being thin film electrodes. Willis teaches that it is known to thin film electrodes that are deposited on the body member and connected to the conductive links to provide a substantially smooth surface resulting in less irritation to the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrodes on the lead as taught by Gotthardt, with the use of thin film electrodes as taught by Willis, since such a modification would provide a lead with electrodes that are thin film electrodes that are deposited on the body member and connected to the conductive links to provide a substantially smooth surface resulting in less irritation to the body.

Claims 4-9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gotthardt in view of Willis.

Gotthardt in view of Willis discloses the claimed invention except for the outer diameter of the lead being about 2 French and internal diameter being 0.012 inch (claim 4), the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.992 inch high (claim 5), the conductors having an angle between each turn of 10 to about 80 degrees (claim 7) and the electrodes being in overlapped relation (claim 14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Gotthardt in view of Willis, with an outer diameter of the lead being about 2 French and internal diameter being 0.012 inch (claim 4), the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.992 inch high (claim 5), the conductors having an angle between

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each turn of 10 to about 80 degrees (claim 7) and the electrodes being in overlapped relation (claim 14) since it was known in the art that leads have: an outer diameter of the lead being about 2 French and internal diameter being 0.012 inch to allow the lead to unobtrusively be placed in small areas of the body and to prevent tissue damage and irritation (claim 4); the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.992 inch high (claim 5) to provide a small diameter lead with flexibility in particular directions; the conductors having an angle between each turn of 10 to about 80 degrees to provide greater or lesser stiffness and flexibility; and the electrodes being in overlapped relation to provide different pulses to or bipolar pulses to a specific area in the body.

In addition, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead as taught by Gotthardt in view of Willis with the outer diameter being about 2 French and internal diameter being 0.012 inch (claim 4), the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.992 inch high (claim 5), and the conductors having an angle between each turn of 10 to about 80 degrees, because Applicant has not disclosed that the outer diameter being about 2 French and internal diameter being 0.012 inch (claim 4), the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.992 inch high (claim 5), and the conductors having an angle between each turn of 10 to about 80 provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the thin electrode lead having circular conductors in a helical pitch as taught by Gotthardt in view of Willis because it will provide a small body implantable flexible lead that is easily and quickly produced.

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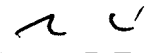
Therefore, it would have been an obvious matter of design choice to modify Gotthardt in view of Willis to obtain the invention as specified in the claim(s).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612.

The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703 306-4520 for regular communications and 703 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1148.


George R Evanisko
Primary Examiner
Art Unit 3762

10/30/02

GRE
October 30, 2002